UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

v.

CORERX, INC.,

Defendant.

Case No. 1:21-cv-10656

PUBLIC REDACTED VERSION

PLAINTIFF BIONPHARMA'S BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Charles A. Weiss
Marisa Marinelli
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
Tel: (212) 513-3200
Fax: (212) 385-9010
Charles.Weiss@hklaw.ccom
Marisa.Marinelli@hklaw.com

Attorneys for Plaintiff, Bionpharma Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

Plaintiff Bionpharma Inc. ("Bionpharma") respectfully submits this brief in support of its motion for a preliminary injunction compelling defendant CoreRx, Inc. ("CoreRx") to supply a critical and unique pharmaceutical product as required by the parties' contract.

Bionpharma and CoreRx had enjoyed a mutually beneficial, productive business relationship dating back years, which included contracts for CoreRx to research and develop, and then later commercially supply, enalapril maleate oral solution product (the "Product") on behalf of and to Bionpharma. (Krishnan Decl. ¶ 5).[1] The contract for commercial supply of Product (the "Agreement") is at issue here. (Ex. F).[2]

On November 30, 2021, CoreRx, without explanation, faxed Bionpharma a letter stating that CoreRx would be "unable to supply" the Product effective immediately. It has refused, however, to tell Bionpharma why it is purportedly "unable to supply," although its staff told Bionpharma personnel by phone that it was a "decision by management" and confirmed that there are no issues with quality. (Krishnan Decl. ¶ 22). When confronted with these statements in a phone call between the principals held on December 7, CoreRx's corporate lawyer dismissed them as "hearsay" and refused to let his client's CEO provide any information, stating that CoreRx was not required by the contract to explain itself.

What is clear is that CoreRx did not suffer a force majeure event that would make its supply of Product impossible. What is also clear is that CoreRx's sister company, Azurity Pharmaceuticals, Inc. ("Azurity")—which sells the branded version of Bionpharma's generic product at monopoly pricing that costs patients up to quadruple the price of Bionpharma's

[1] The Declaration of Venkat Krishnan, submitted concurrently herewith.
[2] Exhibits A-E refer to Exhibits A-E to the Complaint in this case. Exhibits F-O refer to Exhibits to the Declaration of Venkat Krishnan, submitted concurrently herewith. Exhibit P refers to the Exhibit to the Declaration of M. Marinelli, submitted concurrently herewith.

generic—represented in court on December 7 that it had recently entered into some sort of agreement with CoreRx. The details of the collusion between these sister companies remains to be exposed, but all indications are that CoreRx is refusing to honor its contractual obligations to Bionpharma at the behest of and/or for the benefit of its sister company's competing sales. But even if this is not the case, the facts remain that (i) CoreRx is in willful breach of its contractual supply obligations to Bionpharma; (ii) Bionpharma will suffer irreparable harm if it cannot in turn supply the Product to pharmacies; and (iii) the patients who benefit from access to Bionpharma's lower-cost, FDA approved generic will suffer if they are left at the mercy of Azurity's monopoly pricing to obtain (assuming they can afford it) their medicine.

CoreRx's breach has caused, and is continuing to cause, catastrophic loss of reputation, goodwill, and irreparable damage to Bionpharma's business relationships. (Krishnan Decl. ¶ 30-33). Bionpharma's customers do not care that the supply failure for the Product is the fault of Bionpharma's upstream manufacturer; they have contracts requiring Bionpharma to supply Product, and will blame Bionpharma when those contracts are breached. (*Id.*). Bionpharma's customers for its Product are the very same customers for every other generic drug product sold by Bionpharma; this one failure will taint Bionpharma's entire business. (*Id.*).

On the other hand, restoring the *status quo ante* will place the parties back in the positions they would have been in but for CoreRx's breach. CoreRx will not be harmed by restoration of the prior circumstances, let alone harmed to the immense and irreparable degree of Bionpharma is and will be absent an injunction. Finally, unless immediately enjoined, CoreRx's actions will have the real-life effect of removing the sole generic enalapril maleate oral solution from the marketplace, with the effect of driving up prices of this drug for patients and their families.

Bionpharma provides herein clear and convincing evidence that (1) it is likely to succeed in its breach-of-contract claim against CoreRx; (2) it is irreparably harmed by CoreRx's misconduct; (3) the balance of hardships squarely favors preservation of the *status quo ante*, i.e., enjoining CoreRx to perform under the Agreement; and (4) the public interest is strongly served through granting the requested preliminary injunction. This Court should preliminarily enjoin CoreRx to perform under the Agreement by supplying Bionpharma with Product.

STATEMENT OF FACTS

Bionpharma's Product is an oral liquid formulation of enalapril maleate, a drug that had been approved for decades in the form of tablets. (Krishnan Decl. ¶ 35). Enalapril maleate is approved for the treatment of cardiac conditions; specifically, hypertension. (*Id.*). Many children also suffer from these conditions, but have difficulty taking medication as tablets. (*Id.*). Bionpharma's Product is formulated as an oral liquid, and this makes it much easier to use for children suffering from such conditions. (*Id.*). As such, children are the primary patients using Bionpharma's Product. (*Id.*).

Bionpharma went through years of patent litigation against the brand drug owner, Azurity, and its predecessors to finally obtain a judgement that its Product would not infringe Azurity's patents and clear the final hurdle for Bionpharma to launch its Product commercially, which it did on August 17, 2021 after receipt of FDA final approval. (Krishnan Decl. ¶¶ 7-9). By virtue of Bionpharma's ingenuity in designing a non-infringing product, and accepting the risk and burden of lengthy patent litigation against the branded drug owner, Bionpharma obtained 180 days of generic exclusivity, during which time FDA may not approve any other generic version of the Product. (Krishnan Decl. ¶ 7; *see also* 21 U.S.C. § 355(j)(5)(B)(iv)). This exclusivity window, which runs through April 2022, is extremely valuable to Bionpharma, creating a period in which Bionpharma can enjoy substantial revenues to recoup the costs of the underlying patent litigations.

(*Id.*). Additionally, Bionpharma's status as a first-filer gives it several other advantages, such as a first-mover advantage with respect to customers of wholesale generic drugs, and industry acclaim and recognition. (*Id.*).

During the pendency of this patent case, in mid-2019, the brand drug owner's predecessor, Silvergate Pharmaceuticals, Inc. ("Silvergate") was acquired by a capital company, NovaQuest Capital Management, LLC ("NovaQuest"). In or around January 2021, CoreRx was also acquired by NovaQuest, putting control of the supply of Bionpharma's Product ultimately in the hands of the same individuals who own its brand-name competitor, Epaned. (Compl. ¶ 23). Presently, of the seven members of the board of directors of CoreRx, five are also on the board of directors of Azurity. (*Id.*).

In November 2020, Bionpharma and CoreRx entered into the Agreement requiring CoreRx is to supply Bionpharma's requirements of Product, and Bionpharma is to purchase its requirements of the Product from CoreRx. (Krishnan Decl. ¶ 6; Ex. F, Section 5.1). The purpose of the Agreement is for Bionpharma to acquire Product for resale in the wholesale market for generic pharmaceuticals.

Bionpharma holds approved Abbreviated New Drug Application ("ANDA")[3] No. 212408 for Product, and commenced selling its Product pursuant to that approval on or about August 17, 2021. In order to obtain approval of its ANDA for the Product and maintain freedom to sell the Product, Bionpharma expended and continues to expend significant resources to defeat claims for

[3] An Abbreviated New Drug Application is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. The application contains data which is submitted to the FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references. *See* https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

patent infringement filed against it by Azurity, which holds the marketing authorization for Epaned,

The details of Azurity's relentless and fruitless campaign to litigate Bionpharma out of the market with frivolous patent infringement suits are set forth in paragraphs 11-14 of the Complaint. For purposes of this motion, the most pertinent facts are that Azurity (i) lost two cases against Bionpharma; (ii) lost a preliminary injunction motion in a subsequent third case against Bionpharma; and (iii) dismissed two suits against its sister company CoreRx to fabricate grounds for CoreRx to breach its obligation under the Agreement to supply Product to Bionpharma.

Bionpharma last placed a Firm Order under the Agreement on August 26, 2021 for [redacted] of Product by way of Purchase Order No. PO4500001497. (Krishnan Decl. ¶ 24; Ex. M). Under the Agreement, CoreRx must accept and fulfill, and may not modify, cancel, or reject any Firm Order. (Krishnan Decl. ¶ 24; Ex. F). To date, CoreRx has shipped [redacted] of Product purchased pursuant to that order, leaving [redacted] outstanding. (Krishnan Decl. ¶ 24).

On November 19, 2021, CoreRx sent to Bionpharma a letter discussing pricing for products manufactured by CoreRx for Bionpharma. (Krishnan Decl. ¶ 13; Ex. I). In this letter, CoreRx stated that it intended to change the transfer price of several products including the Product; specifically, CoreRx demanded a new transfer price of [redacted]. (*Id.*). This represents an increase of [redacted], more than doubling the cost to Bionpharma. This letter also disclosed the cost of the active ingredient for the upcoming year: [redacted], the exact same cost as for the previous year. (*Id.*; Ex. F at Attachment B).

Bionpharma responded to CoreRx's letter, stating that the "Agreement provides that the Transfer Price is 'the price agreed by the Parties' as specified in the attachment ([redacted]), and can be 'mutually amended from time to time.' There is no provision for CoreRx to unilaterally

take a price increase, and the information CoreRx provided shows that the API cost remains unchanged." (Krishnan Decl. ¶ 14; Ex. J). Bionpharma proposed that the price of the products (including Bionpharma's Product) remain the same as the previous year. (*Id.*).

On November 30, CoreRx sent a facsimile message to Bionpharma stating that "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for Bion's Epaned product. In accordance with Section 5.11 of the Master Manufacturing Supply Agreement that addresses Supply Interruptions, CoreRx will work with Bion to secure an alternative source of supply for this product." (Krishnan Decl. ¶ 16; Ex. K). Bionpharma responded to CoreRx's correspondence on December 1, noting that CoreRx had not provided any rationale for the purported inability to supply product, and that it was in breach of the Agreement. (Krishnan Decl. ¶ 18; Ex. L). On December 7, 2021, the parties met by teleconference, with their respective counsel present. On that call, CoreRx refused to explain the nature of the purported supply interruption. (Krishnan Decl. ¶¶ 21-23). CoreRx further informed Bionpharma that the outstanding Product from PO4500001497 will never be delivered. (*Id.*). These acts are clear and wanton breach of the Agreement.

On December 3, 2021, Bionpharma placed another Firm Order for [redacted] of Product pursuant to Purchase Order No. PO4500001835. (Krishnan Decl. ¶ 23; Ex. N). CoreRx has not acknowledged receipt of this order.

LEGAL ARGUMENT

The purpose of a preliminary injunction is to preserve the relative positions of the parties. *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). The status quo is the parties' pre-controversy position vis-à-vis the other. *N. Am. Soccer League, LLC v. United States Soccer Fed'n, Inc.*, 883 F.3d 32, 37–38 (2d Cir. 2018). A party seeking a preliminary injunction must demonstrate: (1) a likelihood of success on the merits or sufficiently serious questions going to the

merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the plaintiff's favor; (2) a likelihood of irreparable injury in the absence of an injunction; (3) that the balance of hardships tips in the plaintiff's favor; and (4) that the public interest would not be disserved by the issuance of an injunction. *Benihana, Inc. v. Benihana of Tokyo*, 784 F.3d 887, 895 (2d Cir. 2015). A preliminary injunction may be "warranted on the strength of the[ ] first two factors alone." *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 86 (2d Cir. 2020).

I. Bionpharma is Likely to Prevail in its Breach of Contract Claim

"A contract is a contract. From it flow rights and obligations. Anxiety, nervousness, or "buyer's remorse" about the wisdom of the contract does not absolve one from complying with all of the terms of that contract. Unilateral action is abhorrent to the very nature of a mutual, binding commercial agreement." *Eastman Kodak Co. v. Collins Ink Corp.*, 821 F. Supp. 2d 582, 589 (W.D.N.Y. 2011). A requirements contract between Bionpharma and CoreRx for the manufacture and supply of Product existed and was in force; Bionpharma has performed and CoreRx has suddenly refused to perform. There can be no serious dispute that CoreRx has breached the Agreement.

Under New York law, a party alleging breach of contract must establish: (i) the formation of a contract between the parties; (ii) performance by the plaintiff; (iii) failure of defendant to perform; and (iv) damages. *Orchard Hill Master Fund Ltd. v. SBA Commc'ns Corp.*, 830 F.3d 152, 156 (2d Cir. 2016). Bionpharma has established each of those elements.

A. There is a Valid Contract Between Bionpharma and CoreRx

In November 2020, Bionpharma and CoreRx entered into the Agreement. (Krishnan Decl. ¶ 6; Ex. F). The parties performed under the Agreement from November 2020 through November 30, 2021, during which time, Bionpharma has sold to customers approximately [redacted] of Product. (Krishnan Decl. ¶ 25). The Agreement provides certain provisions for termination, but

no such provision has been invoked (or could be invoked) by CoreRx. (Ex. F § 14). More specifically, the Agreement may be terminated only under the following scenarios:

- Five (5) years from the commercialization of the last Product;
- Mutually agreed upon in writing;
- FDA issues a "Refusal to File" for a Product;
- FDA determines that the formulation is not eligible for final regulatory approval in the absence of efficacy or clinical studies;
- Bion may terminate in event of Supply Interruption;
- Bion may terminate in event of Force Majeure;
- Bion may terminate in event of injunction enjoining Bionpharma's sale of Product;

(*Id.*). None of those events have taken place. And notably, none of these events are at the discretion or option of CoreRx. Accordingly, there is a valid, in-force contract between the parties.

B. Bionpharma has Performed As-Required by the Agreement

CoreRx has not, and cannot allege any breach of the Agreement by Bionpharma, for the simple reason that Bionpharma has performed exactly as required, and indeed has gone above and beyond to satisfy its requirements under the Agreement. (Krishnan Decl. ¶ 19).

C. CoreRx has Failed to Perform under the Contract

The Agreement, being a requirements contract, requires CoreRx to manufacture Product for Bionpharma. (Ex. F § 5.1). Specifically, the Agreement provides that:

> CoreRx shall Manufacture and supply to Bion, and Bion shall purchase from CoreRx, Product that is ordered by Bion pursuant to Firm Orders submitted in accordance with this Agreement. … each Firm Order shall be considered a separate Firm Order and shall be valid and binding upon its submission by Bion in accordance with this Agreement." (*Id.*). The Agreement further provides that: "CoreRx will acknowledge all Firm Orders within five (5) days following receipt of same and will deliver all orders within ninety (90) days following the date such Firm Order is received." (Ex. F § 5.4).

CoreRx breached in at least three ways. ***First***, CoreRx's November 30 a facsimile message to Bionpharma stated that "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for Bion's Epaned product." (Krishnan Decl. ¶ 16; Ex. K). CoreRx's declaration that it will not perform under the Agreement is a breach. *Sokol Holdings, Inc. v. BMB Munai, Inc.*, 438

F. App'x 45, 47 (2d Cir. 2011) ("[t]o establish an anticipatory breach under New York law, appellants must show … a statement by the obligor to the obligee indicating that the obligor will commit a breach that would of itself give the obligee a claim for damages for total breach") (internal quotation marks omitted).

Second, Bionpharma's August 26, 2021 Purchase Order No. PO4500001497 was a Firm Order under the Agreement on for [redacted] of Product. (Krishnan Decl. ¶ 24; Ex. M). To date, CoreRx has shipped [redacted] of Product purchased pursuant to that order, leaving [redacted] outstanding. (Krishnan Decl. ¶ 24). During the parties' December 7 teleconference, CoreRx informed Bionpharma that the balance of this order would not be delivered. (Krishnan Decl. ¶ 23). This failure to fulfill Firm Order PO 4500001497 constitutes a second breach.

Third, Bionpharma is entitled under the Agreement to submit Firm Orders for additional Product, provided that those Firm Orders are otherwise in accordance with the terms of the Agreement. Bionpharma submitted a Firm Order for [redacted] of Product pursuant to Purchase Order No. PO4500001835 on December 3, 2021, which CoreRx did not acknowledge within the required five days. (Ex. N; Krishnan Decl. ¶ 24). This refusal to accept additional Firm Orders, and failure to acknowledge them as required, constitutes a third breach.

D. Bionpharma has been Damaged by CoreRx's Breach

Bionpharma is irreparably harmed, and continues to be irreparably harmed by CoreRx's breach. As the sole distributor of FDA-approved generic Product in the United States, Bionpharma is party to numerous distribution agreements to ensure that its Product is available to all those patients in need. (Krishnan Decl. ¶ 31). Bionpharma's relationships with those parties to which it has contracted are in serious jeopardy, as is Bionpharma's industry reputation and goodwill. (Krishnan Decl. ¶¶ 30-33). Bionpharma's failure to meet its customers' needs will paint

Bionpharma as an unreliable partner, and damage its future business prospects in the highly competitive wholesale generic pharmaceuticals marketplace. (*Id.*).

Beyond this irreparable harm, Bionpharma is suffering significant monetary harm in that it is losing high-value sales during a highly lucrative period in which it has no generic competition. (Krishnan Decl. ¶ 7). Additional monetary losses will result from the expense needed to identify and qualify a new manufacturer, a process that will cost in the hundreds of thousands of dollars and will take no less than nine months to complete and bring online. (Krishnan Decl. ¶ 34).

The case is simple – the parties have a contract and CoreRx coldly decided not to honor it, to directly benefit Bionpharma's competitor. Bionpharma will succeed on the merits of its case.

II. Bionpharma is Irreparably Harmed by CoreRx's Breach

CoreRx's breach has caused, and is continuing to cause, irreparable harm to Bionpharma. A movant can establish irreparable harm if it shows that "there is a continuing harm which cannot be adequately redressed by final relief on the merits and for which money damages cannot provide adequate compensation." *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002) (internal quotation marks and citations omitted). Failure to supply a unique product under a requirements contract has been found in several cases to create irreparable injury entitling the buyer to a preliminary injunction.

This issue is not new to this Court or courts in this Circuit. In *Reuters Ltd. v. United Press Int'l*, 903 F.2d 904 (2d Cir. 1990), Reuters had contracted with United Press to provide unique photographs from Europe to United Press, in support of United Press' news reporting. United Press alleged that the unique photographs enhanced the marketability of its products, and that they were not easily replaceable. The Second Circuit concluded that United Press had shown irreparable harm because, if Reuters were allowed to terminate the parties' agreement, United Press would be unable to continue supplying the photographs provided by Reuters to its customers,

which would cause harm to United Press's reputation and the loss of goodwill, and noted that such an injury is "nearly impossible to value." *Id.* at 908. "In cases where a preliminary injunction has issued to prevent a product source from suspending delivery to a distributor, the irreparable harm has often consisted of the loss of customers and the competitive disadvantage that resulted from a distributor's inability to supply its customers with the terminated product." *Id.* at 909; *see also, e.g., John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc.*, 588 F.2d 24, 29 (2d Cir. 1978) (irreparable injury shown when "plaintiff is deprived totally of the opportunity to sell an entire line of merchandise and may incur injury to its goodwill and reputation 'as a dependable distributor'").

In *Rex Medical L.P. v. Angiotech Pharmaceuticals (US), Inc.*, 754 F. Supp. 2d 616 (S.D.N.Y. 2010), Angiotech was the sole worldwide distributor of a product called Option, which it attempted to cease selling to its customer, Rex Medical for purely economic reasons. *Id*. at 620, 622. In granting the preliminary injunction, the court reasoned that if Angiotech were permitted to stop selling Option, Rex Medical would need to find a replacement distributor resulting in Rex Medical's product being off the market entirely, leading its customers to purchase a competing product and perhaps resulting in a permanent loss of business. *Id*. at 623. And while the Court understood that Rex could eventually find an alternative distributor, completely halting the sale of Option harmed Rex's reputation and goodwill in ways that cannot be valued. *Id*.

In *Eastman Kodak Co. v. Collins Ink Corp.*, 821 F. Supp. 2d 582 (W.D.N.Y. 2011), the court considered whether a supplier's failure to provide difficult-to-replace ink constituted irreparable harm in granting an injunction. The court found that the supplied ink product is not easily replaceable, that the ink was needed by end users for very specific purposes and could not easily be replaced by Kodak, which, in reliance on its contract for its supplier to provide it with a steady supply of ink, had not amassed or maintained any stockpile. *Id*. at 589. The court held that

Kodak's inability to provide such ink to its customers therefore threatened its goodwill, the loss of which could not easily be quantified or reduced to a dollar amount. *Id*.

The matter at bar squares closely with *Reuters, Rex Medical*, and *Kodak*, and the same factors weighing in favor of a finding of irreparable harm in those cases are likewise present here. There can be no serious dispute that the Product supplied by CoreRx to Bionpharma is not easily replaced. The manufacture and distribution of Bionpharma's Product is governed by federal law and FDA regulations, and Bionpharma may not distribute any Product manufactured outside of the exact parameters of its ANDA, which designates CoreRx as the manufacturer. In reliance on its contract, Bionpharma has not amassed a stockpile of Product nearly sufficient to meet its customers' needs for anywhere near the length of time it would take Bionpharma to identify and qualify an alternate manufacturer, a process that is costly, uncertain, and will take months or even years. (Krishnan Decl. ¶ 34).

The world of wholesale generic pharmaceutical distribution is small and highly competitive. (Krishnan Decl. ¶ 28). Many generic pharmaceutical products are commoditized, resulting in nearly-identical pricing from distributors such as Bionpharma and its competitors; customers such as pharmacy chains rely heavily on existing business relationships and industry reputation in deciding from whom to purchase products. (*Id.*).

Bionpharma currently enjoys a reputation as a reliable and innovative generic pharmaceutical distributor, with its Product standing out for being unavailable from any of Bionpharma's competitors. (Krishnan Decl. ¶¶ 26-27). Bionpharma's business is strongly reliant on its performance to its customers, and a failure to perform would be devastating to its reputation and future prospects. (Krishnan Decl. ¶ 30). If Bionpharma is unable to supply its customers' needs with respect to Product, its reputation and goodwill as a whole will suffer. (*Id.*). This loss

of reputation will tarnish Bionpharma's entire business, resulting in far more damage than simply lost sales for Product. (*Id.*). For example, the black mark of failing to fulfill its customers' needs will severely prejudice Bionpharma as it seeks to sell additional products to those exact same customers. (Krishnan Decl. ¶ 33). Furthermore, in this particular case, Bionpharma has entered into contracts with several customers for continued supply of its Product, and will be in breach of those contracts because of CoreRx's conduct here. (Krishnan Decl. ¶ 31). Finally, under 21 U.S.C. § 356C(a), Bionpharma will be required to provide written notice to FDA concerning an interruption of the manufacture of the Product likely to lead to a meaningful disruption in the supply of enalapril maleate oral solution, which will be made public. (*Id.*). In addition to the indisputable monetary loss that Bionpharma will suffer as a breaching party, its inability to fulfill its obligations will be laid public, a veritable death sentence in an industry where relationships and reputation are paramount. (Krishnan Decl. ¶ 32-33).

In short, Bionpharma is facing irreparable and catastrophic loss of goodwill in the industry. Bionpharma spent years in preparation of launching its Product, which gave it inroads to new customers and boosted its entire reputation and business. The sudden loss of this product due to CoreRx's wrongful breach more than reverses any gain that Bionpharma had made and paints them as an unreliable partner and distributor to be avoided. Bionpharma is irreparably harmed by CoreRx's conduct.

III. The Balance of Hardships Favor an Injunction

The Court must consider whether the balance of hardships between the plaintiff and defendant "tips in the plaintiff's favor." *Safran Elecs. & Def. SAS v. iXblue SAS*, 789 F. App'x 266, 269 (2d Cir. 2019). Here, the tip of the balance is clear: CoreRx will suffer no harm whatsoever in continuing to perform its duties under the Agreement entered and complied with until approximately two weeks ago, while on the other hand, for the reasons described in detail

above, Bionpharma will suffer immense, irreparable harm. It is not necessary to reiterate the extensive damage that will be suffered by Bionpharma should CoreRx be allowed to continue its wrongful conduct in continuing to breach the Agreement, in addition to crippling money damages which will be later litigated.

On the other side of the ledger is any potential harm that could be suffered by CoreRx should it be enjoined; the answer is zero. CoreRx will be enjoined to continue making Product (as they have for over one year), and will be paid for that product (as they have been). A party is simply not harmed by being forced to live up to its contractual duties. Even to the extent that CoreRx will stand to lose money in continuing to sell Product to Bionpharma, losses incurred from being required to perform contractual obligations did not outweigh significant harms suffered by innocent partners. *See Rex Med.*, 754 F. Supp. 2d at 625-26 ("Angiotech supports its attempt to circumvent its contractual obligations by arguing that performance of the Agreement is a severe hardship on the company. This is an argument Angiotech should save for a bankruptcy court—if it seeks bankruptcy protection—and does not support a conclusion that Rex should bear the burden of Angiotech's poor decisionmaking").

In short, there is no basis to find that CoreRx would be harmed in any way through the issuance of an injunction, let alone harmed to the same or greater degree as Bionpharma. The balance of hardships favors granting the injunction.

IV. The Public Interest is Served in Granting an Injunction

The public interest is served in two separate and distinct ways through granting injunctive relief here. ***First***, freedom of contract is itself a strong public policy interest in New York. *159 MP Corp. v. Redbridge Bedford, LLC*, 128 N.E.3d 128, 133 (2019). The public has an interest in seeing that parties oblige by their contractual obligations and are not allowed to skirt such obligations at another's expense. *See, e.g., Baltimore & O. S. W. Ry. Co. v. Voigt*, 176 U.S. 498,

505, 20 S. Ct. 385, 386, 44 L. Ed. 560 (1900) ("[T]he usual and most important function of courts of justice is rather to maintain and enforce contracts, than to enable parties thereto to escape from their obligation on the pretext of public policy"). For this reason, enforcing the terms of the Agreement entered into freely by these sophisticated parties serves the public interest.

Second, public policy is strongly served in that a denial of an injunction here has the effect of removing the sole generic option for otherwise cost-prohibitive drug used to treat severe cardiac disease mostly in children would be devastating to patients and families. The desperate public need for generic competition for Epaned has been prominently featured in the news media, including the Washington Post, which noted that Epaned falls into a category of drugs where the brand (Azurity) creates a liquid formulation of an old drug and charges exorbitant prices for the reformulated drug, posing an incredible financial burden to families. Shefali Luthra, *The dilemma of kid-friendly pharmaceuticals: Safety comes at a steep price*, WASHINGTON POST (Apr. 21, 2017).

This public interest was expressly considered and found persuasive by Judge Stark in the District of Delaware, when weighing whether to enjoin Bionpharma from selling Product during the pendency of the most recent baseless patent infringement claim brought by Azurity. Judge Stark stated: "Those circumstances now include a defendant competing in the marketplace against the plaintiff, competing with the lower-priced generic drug product. The price -- I'm sorry -- product that individual patients are using and relying. … Even if that were not the case, I turn to the public interest. And I think under the circumstances here, considering the totality of the circumstances, the public interest does not support the requested injunction which, again, would require the Court to remove from the market a lower-priced generic drug product on which some number of patients are relying." (Ex. P at 109:6-10, 109:25-110:6). Permitting CoreRx to continue

its breach is egregiously contrary to the public interest here especially, where Product is specifically designed for use by children suffering from cardiac conditions. (Krishnan Decl. ¶ 35).

Here, brand-name Epaned is priced to consumers at approximately $560 per bottle, while Bionpharma's Product is priced at approximately $180 per bottle. As discussed above, there is no third option. The denial of an injunction here removes Bionpharma's lower-priced generic product from the market and has the practical effect of driving up the cost of enalapril oral solution fivefold, a cost that will be borne by patients and families solely to further enrich the ownership of CoreRx.

Beyond just the difference in marked retail price, most patients will pay substantially less for Bionpharma's Product compared to Epaned because most major prescription drug insurers cover the cost of generic drug products for very low patient co-pay. (Krishnan Decl. ¶ 36). For example, a typical co-pay for an insured patient purchasing generic medication would be $5 or $10. (*Id.*). Coverage for branded products is often far less robust, leaving patients to pay a higher percentage of the higher retail price, and therefore a much higher total amount. (*Id.*).

When generic version of a drug product is available, most prescription drug insurers designate the generic as the preferred product, and will either provide no coverage for the branded product or potentially coverage only with a much higher patient copay or with prior authorization from the prescribing physician. (Krishnan Decl. ¶ 37). This business model was thoroughly explained in *Abbott Laboratories v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 844 (N.D. Ill. 2007), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008), where Judge Coar meticulously analyzed the impact at the patient-level regarding the entry of a generic drug into the market, stating:

> Most prescription drug purchases in the United States are paid for, at least in part, by employer-sponsored health insurance plans or by government programs like Medicaid. When a pharmaceutical enters the market, insurance companies, managed care organizations, and Medicaid plans decide whether to place the drug on their pharmaceutical formularies. The formulary is a list of approved medications for which the plan will pay some part of the cost. These formularies

> are, in many instances, divided into three tiers. The first tier comprises low cost generic products. The second tier comprises "preferred branded" products. The third tier comprises "non-preferred branded" products. Patients must pay more out-of-pocket for drugs listed on a higher tier than for a drug of the same price listed on a lower tier. The managed care provider typically pays more for drugs listed on a lower tier (e.g., Tier 1) than for a drug of the same price listed on a higher tier (e.g., Tier 3). The Medicaid formulary does not have tiers; either a drug is listed on the formulary (also known as the preferred drug list) or it is not. If the drug is not on the Medicaid formulary, the program will not cover any portion of its cost. If a doctor prescribes a non-formulary drug to a Medicaid patient, the patient must pay the entire cost out-of-pocket.
>
> When a generic version of a branded product enters the market, managed care providers generally add the generic to their formulary on Tier 1. They will then move the branded product to a higher position (e.g., from Tier 2 to Tier 3). Some plans will remove the branded drug from their formulary altogether. If the generic product is AB rated, meaning that the FDA considers it therapeutically equivalent to the branded product, many pharmacies will substitute the generic product for the branded product unless the physician specifies on the prescription form "Dispense as Written." Medicaid programs typically remove branded products from their formularies altogether once a generic has entered the market. … Once a managed care organization moves a drug to a higher tier on its formulary or, in the case of Medicaid, removes the drug entirely, it is costly and difficult to regain a preferred position.

Id.

If, because of this supply interruption from CoreRx, Bionpharma is unable to satisfy the demand nationwide for the Product, the Product will start becoming unavailable on a patchwork basis from pharmacy to pharmacy. (*Id.*). For example, one pharmacy chain may still have the Product in stock, but only at some of its locations. (*Id.*). A different pharmacy chain as well as many independent local pharmacies may have no inventory at all. (*Id.*). Similarly, one distributor/wholesaler may have Product in its inventory to supply to pharmacies, while another distributor/wholesaler may have run out. (*Id.*). The result as indicated above is a unpredictable patchwork of Product being available at some pharmacies but not at others. (*Id.*).

Prescription drug insurers do not adjust their coverage in real time. (Krishnan Decl. ¶ 38; *Abbott Labs.*, 500 F. Supp. 2d at 844). Accordingly, if there is a shortage of Product caused by

the supply interruption from CoreRx, the prescription drug insurers will not automatically or quickly resume providing coverage for the branded product Epaned. (*Id.*). The result is that a patient, or more likely, the patient's parent, will face the situation at the pharmacy that the pharmacist cannot fill the prescription with the Product because it is out of stock, but the patient's insurance will not cover the branded product Epaned. (*Id.*). If the customer is unable to pay the uninsured cash price for Epaned, he or she will not be able to have the prescription filled. (*Id.*). The customer could potentially seek out other pharmacies to find one that accepts the patient's insurance and has the generic product in stock, but this can be difficult depending in part on how many pharmacies are within the patient's vicinity. (*Id.*). This situation will exacerbate as supply of Product continues to dwindle nationwide. (*Id.*).

Adding to the difficulty is the fact that most prescriptions are provided electronically to a specific pharmacy identified by the patient to the prescribing physician. (Krishnan Decl. ¶ 39). There is not, with this system, the familiar paper prescription that the patient can bring to any pharmacy of their choosing. (*Id.*). For example, if the patient's prescription was sent electronically to one pharmacy, but that pharmacy is out of stock of Product, and the patient seeks out another pharmacy, that other pharmacy, even if it does have Product in stock, will not have the patient's prescription. (*Id.*). This would require the patient to either seek a new prescription from the prescribing physician to be sent to the pharmacy with in-stock Product, or to try to get the original pharmacy to transfer the electronic prescription. (*Id.*). Both of these can be challenging and time consuming, again with the result that the patient may not be able to secure a refill of his or her prescription before running out. (*Id.*).

This outcome in no way serves the public interest.

CONCLUSION

For the reasons set forth above, Bionpharma respectfully urges the Court to preliminarily enjoin Defendant CoreRx from taking or omitting to take any action that would prevent CoreRx from supplying Product to Bionpharma under the Agreement.

Respectfully submitted,

HOLLAND & KNIGHT LLP

Attorneys for Plaintiff

DATED: December 13, 2021
New York, New York

By: *s/ Charles A. Weiss*
CHARLES A. WEISS